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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,779	01/02/2001	Gijsbert Johan Jansen	80541	4107

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,779

Applicant(s)

JANSEN ET AL

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,13-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,13,14,17,18,20 and 22 is/are rejected.
- 7) ☒ Claim(s) 7,15,19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action filed on April 25, 2005 has been entered.

Status of the application

3. Applicants' response to the office action is fully considered and found persuasive in part. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL.

4. The following is the rejection made in the previous office action:

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-6, 13-14, 17-18, 20,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolas et al. (USPN. 5,895,752) in view of Sheiness et al. (USPN. 5,700,636).

Nicholas et al. teach a method of claim 1, for identifying the presence of a bacterium in a sample, wherein Nicholas et al. disclose that the method comprises:

(a) testing said sample by gram-staining on a sample fixed on a glass slide and determining the rod or coccus character of said bacterium and determining the gram-positive bacterium with a coccus character (see col. 3, line 1-15); (c) identifying the presence of the bacterium in a sample (see col. 3, line 9-15).

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With regard to claims 2-3, Nicholas et al. teach that said sample is clinical sample comprises mammalian blood (see col. 3, line 28-37);

With regard to claims 5, 13, 17, Nicholas et al. teach detection of bacteria comprising *Klebsiella pneumonia*, *Pseudomonas aeruginosa*, *E.coli* (rod-like gram-negative bacteria), *Streptococci*, *Enterococcus* (gram-positive chain like coccus) and *staphylococcus aureus* (gram-positive clumb-like coccus type) (see col. 3, line 4-42, table.1, col. 4, line 34-43).

With regard to claim 21, Nicholas et al teach that the method comprises one-step procedure for binding bacteria present in the sample on a microscopic slide (see col. 3, line 1-3).

However, Nicholas did not teach use of hybridization probe and lysis buffer comprising lysozyme or proteinase K for further characterization of the bacteria.

Sheiness et al. teach a method of claims 1, for detecting microorganism in biological sample, wherein Sheiness et al. disclose that the method comprises use of lysis buffer and hybridization probe to capture microorganism and detection of said microorganism (see col. 6, line 49-67, col. 7, 1-21). Sheiness et al. also teach said use of lysis buffer with lysozyme or proteinase K depending on the type of bacteria to be detected (see col.3, line 49-67, col. 9, line 1-31). Sheiness et al. also teach when the bacteria to be detected is streptococcus type, the lysis buffer comprises lysozyme and proteianse K (see col. 10, line 59-67, col. 11, line 1-5). With regard to claims 6, 14, 18, Sheiness et al. teach probes to said nucleic acid of microorganism is selected from ribosomal RNA col. 14, line 24-41); with regard to claim 20, Sheiness et al. teach that said hybridization comprises positive and negative controls (see col. 18, line 45-58).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to use the method for detecting the presence of bacteria based on gram-stain as taught by Nicholas et al. with a step of using hybridization probe and lysis buffer as taught by Sheiness et al. for the purpose of developing a sensitive method of detection of a bacterium in a sample. An ordinary practitioner would have been motivated to combine the method of Nicholas et al. with the inclusion of hybridization and lysis buffer because Sheiness et al. explicitly taught the differences in lysing gram-negative and gram-positive bacteria and the lysing conditions to release nucleic acids from rigid cell walls of different types of bacteria (see col.9, line 12-31 col. 5, line 17-36) Sheiness et al. also taught designing capture probes and selection of lysis conditions enhance the sensitivity and specificity of the detection of bacterium in a sample (see col. 14, line 46-56). The ordinary artisan would have a reasonable expectation of success to combine the method for detection of bacterium in a sample based on gram-staining as taught by Nicholas et al. with the hybridization probe and lysis conditions based on gram-stain of bacteria as taught by Sheiness et al. for the purpose of improving the sensitivity and specificity of the detection of a bacterium in a biological sample.

Response to arguments:

6. Applicants' arguments and amendment are entered and fully considered and found persuasive in part.
7. With regard to the objection made in the previous office action to claims 5, 13, 17, the amendment and arguments are fully considered and the objection is withdrawn in view of the amendment.

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8. With regard to the rejection made in the previous office action under 35 USC 112, second paragraph, Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of the amendment.

9. With regard to the rejection of claims 1-3, 5-6, 13-14, 17-18, 20, 22 under 35 USC 103(a) Applicants' arguments are fully considered and found not persuasive. Applicants argue that Nicolas et al. does not teach identifying different bacteria and teaches away from the instant invention and Sheiness et al. suffers the same defect and uses a single lysis buffer to lysis all of the bacteria. Applicants' also argue that the examiner cited the disadvantages of the prior art and the context of its use is not clear to the Applicant. Applicants' further argue that the cited passage does teach the differences in lysing gram-negative and gram positive bacteria, however Sheiness et al. does not teach such treatment using different lysis buffers comprising an enzyme for lysis.

Applicants' arguments are fully reviewed and considered and found not persuasive. First, the instant claim recites identifying the presence of a bacterium in a sample, and the method steps uses a clause "when", and recites four different lysis protocols, which implies that the method could be used to detect one target bacterium at a time and it is not a method for detecting multiple targets at a given time. Thus Nicolas et al. does teach said method for detecting a bacterium in a sample.

Second, with regard to the arguments that Nicolas and Sheiness et al. "teaches away" and cited passage teaches only differences in lysis of different bacteria and does not teach different lysis buffers, Examiner notes that MPEP 2145 states that "A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; however, "the nature of the teaching is highly relevant and must be weighed in

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substance. The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986). Furthermore, "[k]nown disadvantages in old devices which would naturally discourage search for new inventions may be taken into account in determining obviousness." *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966). In the instant invention, Nicolas et al teach a method for detecting a bacterium in a sample and Sheiness et al. disclose or suggest the differences cell wall rigidity of some bacteria and the differences in lysing different bacteria with different lysis buffers, which are considered highly relevant in the present context and are considered as significant factor in determining obviousness, according to MPEP 2145. Further Examiner considers that the cited disadvantages are taken into account as a motivation to modify the teachings of Nicolas et al. in a manner taught by Sheiness et al.

With regard to applicants' arguments that Sheiness et al. does not teach use of an enzyme (proteinase K/ lysozyme), Examiner notes that Sheiness et al. does teach the use of an enzyme as discussed above in passages (col.3, line 49-67, col. 10, line 59-67, col. 11, line 1-5).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, specific motivation is provided in the rejection above, and an ordinary practitioner would have been motivated to combine the method of Nicholas et al. with the inclusion of hybridization

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and lysis buffer because Sheiness et al. explicitly taught the differences in lysing gram-negative and gram-positive bacteria and the lysing conditions to release nucleic acids from rigid cell walls of different types of bacteria (see col.9, line 12-31, col. 5, line 17-36) Sheiness et al. also taught designing capture probes and selection of lysis conditions enhance the sensitivity and specificity of the detection of bacterium in a sample (see col. 14, line 46-56). The ordinary artisan would have a reasonable expectation of success to combine the method for detection of bacterium in a sample based on gram-staining as taught by Nicholas et al. with the hybridization probe and lysis conditions based on gram-stain of bacteria as taught by Sheiness et al. for the purpose of improving the sensitivity and specificity of the detection of a bacterium in a biological sample.

Allowable subject matter

10. Claims 7, 15, 19, 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru
Examiner

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JEFFREY FREDMAN
PRIMARY EXAMINER
6/30/15